

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance : Nitrous Oxide

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
<p>1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]</p>	X			<p>N2O TAP page 7&8 “Nitrous oxide (N2O) added to the atmosphere is a potent greenhouse gas, allowing sunlight in but refusing to allow heat to escape, thus tending to warm the planet.....It’s contribution to the calculated greenhouse effect is roughly 7.5 percent.” N2O TAP page 10 criteria #2 “Nitrous oxide is a potent greenhouse gas with an atmospheric half-life of 120 years” N2O TAP page 14 reviewer 1 criteria #2 “I agree with the criteria evaluation. Use of nitrous oxide, a greenhouse gas.....so it cannot be accomplished without an adverse effect on the environment.” Also considered was a magazine article from Spray Technology & Marketing that was submitted by the petitioner. It states “considering the estimated 140,000,000 aerosol cans per year worldwide that are each pressurized with several grams of nitrous oxide, the total amount of gas used for these whipped creams, and other products can be calculated as about 920 tons per year. Irresistibly, we must then measure this amount against the worldwide annual injection rate of about 450,000,000 tons. It is seen to be an infinitesimal 0.0002 % (or 2ppm) of the total production rate, and not an amount of concern to us from an environmental standpoint.”</p>
<p>2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]</p>	X			<p>Same response as to question #1 above.</p>
<p>3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]</p>	X			<p>Same response as to question #1 above.</p>
<p>4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]</p>			X	
<p>5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]</p>			X	
<p>6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]</p>			X	
<p>7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]</p>			X	
<p>8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]</p>	X			<p>N2O TAP page 8 “The most significant hazard associated with the gas is inhalation of oxygen deficient atmospheres and effects on the central nervous system.”</p>
<p>9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]</p>	X			<p>N2O TAP page 6 criteria #2 “N2O is primarily removed from the atmosphere in the stratosphere by photolysis (breakdown by sunlight).The best estimate of atmospheric lifetime of N2O is 120 years.....In order for atmospheric concentrations to be stabilized near current levels, anthropogenic sources would need to be reduced by</p>

				more than 50%”
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			N2O TAP page 8 criteria #4 The effects of the substance on human health “Cardiovascular: The circulatory effect of nitrous oxide is based on its tendency to affect the sympathetic nervous system.....The most significant hazard associated with this gas is inhalation of oxygen deficient atmospheres and effects on the central nervous system.....At high concentration, unconsciousness or death may occur”
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		N2O TAP page 4 “(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use: (1) The ingredient is used as a propellant, aerating agent, and gas as defined in Sec. 170.3(o)(25).” N2O TAP page 11 response to criteria #5 “Nitrous oxide is an ingredient permitted under 21CFR 184.1545 as a propellant, aerating agent and gas.....”
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	X			Same response as to question # 11 above
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Same response as to question # 11 above And Airgas technical bulletin submitted with petition under “specifications” And MSDS sheet submitted with petition page 1 under “composition and information on ingredients, heading maximum impurities”

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance __Nitrous Oxide

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]	X			N2O TAP page 10 #1 “Nitrous oxide occurs naturally due to the action of soil bacteria. Only synthetic material is commercially available”
2. Is there an organic substitute? [§205.600 b.1]		X		The N2O TAP makes no reference to any other organic substitutes.
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X	X		N2O TAP page 9 “Although nitrous oxide is the currently preferred whipping propellant, other expanding agents may also be used, such as CO2. A Japanese patent application.....nitrogen is used as the propellant and CO2 is the expanding agent; in this aerosol, the nitrogen: carbon dioxide volumetric ratio is 50-90:50-10.” Statement from the petitioner “The use of CO2 as an expanding agent is not possible. He notes that CO2 is an acidic gas, which would react with the water in a dairy whipped cream and cause it to acidify. Use of CO2 in a vegetable based whipped cream as in the case of the Japanese patent application may work if water is not present. Regarding the use of Nitrogen as a whipping propellant: Nitrogen is not fat soluble, and therefore provides no propulsion. He is unaware of any tests that have been done on a gas mixture of N2O and Nitrogen.....”
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		N2O TAP page 10 #1 “Nitrous oxide occurs naturally due to the action of soil bacteria. Only synthetic material is commercially available”
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		N2O TAP page 10 #1 “ Only synthetic material is commercially available”
6. Is there any alternative substances? [§6518 m.6]	X	X		N2O TAP page 9 “ Although nitrous oxide is the currently preferred whipping propellant , other expanding agents may also be used, such as CO2. A Japanese patent application.....nitrogen is used as the propellant and CO2 is the expanding agent; in this aerosol, the nitrogen: carbon dioxide volumetric ratio is 50-90:50-10.” N2O TAP page 20 criteria #7 “Nitrous oxide is used because it is a lipid soluble gas. An alternative is CO2.....However, the use of carbon dioxide is not recommended because it is the primary component of ‘greenhouse gases’, and therefore does not solve the problem” Statement from the petitioner “The use of CO2 as an expanding agent is not possible. He notes that CO2 is an acidic gas, which would react with the water in a dairy whipped cream and cause it to acidify. Use of CO2 in a vegetable based whipped cream as in the case of the Japanese patent application may work if water is not present. Regarding the use of Nitrogen as a whipping propellant: Nitrogen is not fat soluble, and therefore provides no propulsion. He is unaware of any tests that have been done on a gas mixture of N2O and Nitrogen.....”
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Although the committee discussed the alternate practice of whipping cream at home it was agreed that there were no alternative practices mentioned in the N2O TAP for “commercial” applications of a whipped cream.

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices?

Substance __Nitrous Oxide

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]		X		N2O TAP page 6 “The primary result of using nitrous oxide as a propellant is the release of the gas into the air. Since one of the goals of organic farming is to reduce potential environmental damage, an issue would be its contribution to the greenhouse effect.” N2O TAP page 20 criteria #7 “Environmentalists and ecologists share the consensus that there should be an 80% reduction in the total greenhouse gases below the 1990 level and that that would be needed by 2005” and #2 “Nitrous oxide is a potent greenhouse gas with an atmospheric half-life of 120 years” In support of organic compatibility it was pointed out the CO2, another greenhouse gas is listed on the National List. This would be consistent with H and I from the “Compatibility with Organic Production and Handling” document adopted October 24, 2003.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			In support of organic consistency it was pointed out the CO2, another greenhouse gas is listed on the National List. This would be consistent with H and I from the “Compatibility with Organic Production and Handling” document adopted October 24, 2003.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		Same response as #1 above.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			N2O TAP page 10 #3 “...It is inert and does not affect the nutritional value of the food”
5. Is the primary use as a preservative? [§205.600 b.4]		X		N2O TAP page 3 “Specific Uses: 1. Whipping propellant for food grade aerosols. Other Uses #1-6” N2O TAP page 1 Executive Summary “Nitrous oxide was petitioned for use as a whipping propellant for food grade aerosols” N2O TAP page 19 in the reviewer #3 comments “The primary purpose of nitrous oxide in the food is for texture, and does not serve any purpose for food preservation...”
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		N2O TAP page 11 criteria #4 “Nitrous oxide is used as a propellant to recreate the texture of whipped cream, which can not be retained during processing” However that committee discussed this aspect and disagreed. The committee stated that the substance is used to create a texture and does NOT recreate a texture that is lost during processing. N2O TAP page 19 reviewer 3# comments “... and is only temporarily used for texture...”
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	
a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	

c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____	Substance: __ Nitrous Oxide _____																
<p>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="text-align: right;">Criteria Satisfied?</td> </tr> <tr> <td>1. Impact on humans and environment</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No (see B below)</td> </tr> <tr> <td>2. Availability criteria</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility & consistency</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No (see B below)</td> </tr> </table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No (see B below)	2. Availability criteria	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No (see B below)								
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<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: _____</p> <p>_____</p> <p>Basis for annotation:</p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>																
<p>D. Final Board Action & Vote: Motion by: _____ Second: _____</p> <p><u>Vote:</u></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;"></td> <td style="width: 25%;">Nonagricultural</td> <td style="width: 25%;"></td> </tr> <tr> <td>Synthetic</td> <td></td> <td>Not synthetic</td> <td></td> </tr> <tr> <td>Allowed¹</td> <td></td> <td>Prohibited²</td> <td></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Deferred⁴</td> <td></td> </tr> </table> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p> <p>Absent: _____</p> <p style="text-align: center;">1—substance voted to be added as "allowed" on National List</p> <p>Annotation: _____</p> <p style="text-align: center;">2—substance to be added to "prohibited" paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <p>_____</p> <p style="text-align: center;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p>_____</p> <p style="text-align: center;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____</p> <p>_____</p>		Agricultural		Nonagricultural		Synthetic		Not synthetic		Allowed ¹		Prohibited ²		No restriction		Deferred ⁴	
Agricultural		Nonagricultural															
Synthetic		Not synthetic															
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<p>E. Approved by NOSB Chair to transmit to NOP:</p> <p>_____</p> <p>Dave Carter, NOSB Chair _____</p> <p style="text-align: right;">Date</p>																	
<p>F. NOP Action: Include in FR to amend National List: <input checked="" type="checkbox"/></p> <p>Return to NOSB <input checked="" type="checkbox"/> Reason: _____</p> <p>_____</p> <p>Richard H. Mathews, Program Manager _____</p> <p style="text-align: right;">Date</p>																	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: April 2004

Substance: Nitrous Oxide

Committee: Crops Livestock Handling

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

	Criteria Satisfied?
4. Impact on humans and environment	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)
5. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)
6. Compatibility & consistency	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

#1 – fails to satisfy criteria based on answers to Category 1 questions 1, 2, 3, 8, 9, & 10.
 #3 – fails to satisfy Category 3 questions 1 & 3 on compatibility. Satisfies criteria for consistency based on Category 3 question 2.

C. Proposed Annotation: NONE

Basis for annotation:

To meet criteria above: _____ Criteria: _____

Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote: Motion #1 by: Andrea Second: Kevin
 Motion #1 – To consider Nitrous Oxide as a non-agricultural, synthetic material for use in Handling.
 Motion #2 – By Andrea Second Kim -- To allow N2O for addition to 205.6

Vote: Motion #1 Yes: 5 No: 0 Abstain: 0 Absent: 1
 Motion #2 Yes: 0 No: 5 Abstain: 0 Absent: 1

Agricultural		Nonagricultural	<input checked="" type="checkbox"/>	Crops	
Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock	
Allowed ¹		Prohibited ²		Handling	<input checked="" type="checkbox"/>
No restriction		Deferred ⁴		Rejected ³	

1—substance voted to be added as “allowed” on National List

Annotation: _____

2—substance to be added to “prohibited” paragraph of National List

Describe why a prohibited substance: _____

3—substance was rejected by vote for amending National List

Describe why material was rejected: **due to failure to satisfy criteria on environmental and compatibility issues** _____

4-substance was recommended to be deferred

Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Kevin O'Rell

Date: March 2, 2004

